heating element so as to regulate the amount of heat applied by the heating element to the gas within the chamber, thereby maintaining the gas at a desired temperature or within a desired temperature range; and

f) a backup container for liquid and an access tube that couples the backup container to the housing to provide a supply of liquid to the humidification means.

REMARKS

Claims 1-12, 19-23, 38, and 55-71 were pending in the present application. Of these, claims 1-12, 19-23, 38 and 55-71 were rejected by the Examiner. For the following reasons, it is believed that the present application is now allowable.

CLAIM REJECTIONS

35 USC § 112

The Examiner has rejected claims 1-12, 19-23 and 52 as being indefinite. As a preliminary matter, Applicant notes that in the previous Official Action, claims 39-54 were withdrawn by the Examiner from further consideration, thereby rendering the Examiner's present rejection of claim 52 moot.

Claim 1 has been amended to eliminate the limitation "the outlet" in section a, line 2,3.

Claim 1 has been rewritten to describe an apparatus for treating gas prior to the use of the gas in a medical procedure involving a patient. As described, the apparatus is used to heat the gas to a desired temperature range and humidify the gas to a desired relative humidity before delivery of the gas to the patient. The apparatus as claimed includes a backup supply container to ensure that a constant supply of water or other humidifying solution is available to humidify the gas throughout the entire length of the medical procedure. In short, the instant application claims an apparatus for treating gas that is received into the apparatus from a gas source via an insufflator

with heat and humidity, and which includes features heretofore unavailable of allowing the user of the apparatus to ensure that a desired temperature and humidity level is maintained in the treated gas throughout the entire length of the medical procedure.

Claims 6-12, 19-23, 38, and 55-71 have been cancelled by the Applicant, and claims 72-81 have been added.

35 USC § 102

The Examiner has rejected claims 1-12, 19-23, 38, 55-64, 70 and 71 as being anticipated by a Patent No. 5,411,474 previously granted to Ott, et al. ("'474"). It is the Examiner's position that '474 teaches an apparatus for treating a gas comprising a housing defining one chamber having an entry port and an exit port, the chamber that contains a volume of liquid in fluid communication with the insufflator, a humidifying means, a container/reservoir, the device comprising an opening, and a port for filling the container/reservoir, and at least one layer of filter/membrane in the chamber for filtering the gas, water retaining layers and the pre-charging of those layers (p. 2, para. 5 of the Official Action). The Examiner also believes that '474 teaches the use of DC power, humidity sensing means and monitoring means, the use of capacitors and resistors for the humidity sensing means, an operational amplifier, and a control means for controlling electrical power, all of which allow for simultaneous heating and hydration (p. 3, para. 5 of the Official Action).

As previously indicated, claims 6-12, 19-23, 38, and 55-71 have been cancelled by the Applicant. Moreover, Applicant respectfully submits that the instant application is not anticipated by '474 for the reasons that follow. Contrary to the Examiner's position, '474 neither directly nor indirectly teaches a method for sensing or monitoring of humidity levels of the gas. Primarily, '474 specifies that the humidity is not independently controlled (Table 1, col. 11, lines 32-33). Instead, the relative humidity is calculated pursuant to the selected temperature of the gas, selected gas flow rate, and porous bed characteristics (Table 1, col. 11, lines 14-36). Further, there is no feedback loop illustrated on Figure 3 demonstrating any communication or flow of

information between a humidity sensor and the microprocessor of the apparatus. As such, there is no mention of any humidity sensing means in either the specification or the claims of '474. In short, '474 does not directly teach a method for sensing or monitoring the humidity level of the gas.

Further, Applicant disagrees with the Examiner's position that "...'474 at least inherently teaches sensing of the humidity of a gas" (p. 7, para. 14 of the Official Action). There are no sensing devices for pressure or volumetric flow of the gas taught by '474 because control of the pressure and volumetric flow of the gas is not maintained by the apparatus taught by '474. It is clearly specified in the patent that the gas to be treated by the inventive apparatus is "...received from an insufflator which receives gas from a gas source....wherein the gas is pressure- and volumetric flow rate-controlled by the insufflator..." (col. 3, lines 52-58). Therefore, control of the pressure and volumetric flow rate is not performed by the apparatus taught by '474 and actually occurs before the gas is even delivered to the apparatus. The apparatus therefore does not require or include any means for sensing either the pressure or volumetric flow rate of the gas.

In addition, Applicant respectfully disagrees with the Examiner's unsupported conclusion that "...volumetric flow to and from the chamber in combination with the pressure and temperature will inherently control the humidity as controlled in Ott et al. by keeping the temperature within 2 degrees Celsius which is inherently teaching the sensing and controlling of humidity" (p. 7, para. 14 of the Official Action). A gas at any given temperature may have any relative humidity between 0% and 100%. Applicant is unaware of, and the Examiner has not cited to, any direct thermodynamic relationship between temperature and humidity that would control of the humidity level solely by controlling the temperature of the gas.

Finally, Applicant respectfully submits that '474 does not teach an apparatus including multiple water retaining layers as proposed by the Examiner. A review of the patent shows that a "humidification means" is specified by the patent (col 3, lines 63-64; col. 4, line 18; col. 5, line 8; col. 9, lines 59-61; col. 12, claim 1. d), line 1). Subsequently, the humidification means is further described as a "water-containing humidifying bed" (col. 6, lines 35-36, in reference to Fig. 2; col.

8, lines 15, 17, 35 and 37). However, nowhere does the application define the humidification means as comprising single or multiple layers, or even refer to layers in the context of the humidification means. It appears that the Examiner has acknowledged this fact by later stating "'474 teaches all the limitations of the claims except for comprising a plurality of water-retaining layers ..." (p. 4, para. 8 of the Official Action, emphasis added). As such, '474 does not teach the use of water retaining layers.

For the foregoing reasons, the Applicant respectfully submits that the apparatus proposed by the instant application is not anticipated by the apparatus taught by Patent No. 5,411,474.

35 USC § 103

The Examiner has rejected claims 6-11 and 65-69, as being unpatentable over Ott, et al. in view of in view of Absten, et al. (U.S. Patent No. 5,246,419). Although the Examiner does not specify, Applicant presumes the Examiner's reference to Ott, et al. in this portion of the Official Action is to U.S. Patent No. 5,411,474 ('474), as previously referenced, and therefore bases all arguments upon this presumption.

Applicant respectfully disagrees with the Examiner's assessment of the teachings of Absten, et al. Particularly, Applicant respectfully points out that Absten, et al. teaches an apparatus for supplying insufflation gas a high flow rates during laparoscopic surgery (col. 2, line 43-45). Absten, et al. also teaches that one element of the typical embodiment of said apparatus would include a pressure sensor, *i.e.*, at least one pressure gauge, connected to a microprocessor to automatically reduce the gas flow when a predetermined limit is exceeded (col. 5, lines 36-39). Thus, Absten, et al. describes an apparatus including a microcontroller used to measure and maintain gas pressure.

Absten, et al. does not teach the use of the microprocessor for any other purpose other than to respond to pressure sensors that may be included in the inventive apparatus. Absten, et al. specifies that one such pressure sensor may be located in each gas line emanating from a plurality of gas cylinders (col. 4, lines 47-49). It is taught that the microprocessor is used to monitor the pressure in each gas line and turn on additional cylinders sequentially for constant delivery of the

gas to the apparatus (col. 4, lines 50-52). It is also taught that the microprocessor may also be connected to a sensor that directly measures the pressure in the patient (col. 5, lines 30-39).

Absten, et al. does not, however, teach any communication between the microprocessor and any sensor for monitoring of the humidity levels of the gas. There is no loop indicated on either Fig. 2 or Fig. 3 of Absten, et al. where information may be communicated from a sensor to the microprocessor. Absten, et al. does not teach use of the microprocessor for humidity monitoring means. As such, there is no indication that the microprocessor taught by Absten, et al. could be combined with '474 to produce an apparatus that could monitor the humidity levels of the gas.

The Examiner's instant rejection is also based upon the position that that it would be obvious to add an AC/DC converter to Ott, et al (p. 4, para. 7 of the Official Action). Applicant respectfully disagrees with the Examiner's statement. A source of DC power is described in the application because such power is needed to supply power to the heater/hydrator and the alarm circuit included in the apparatus. DC power is desirable because it provides power at a low voltage, thereby protecting the patient from exposure to high voltage electricity and the risk of shock.

However, no AC/DC converter is claimed as part of the inventive apparatus. In fact, it is further specified in the application that DC power provided by battery or photovoltaic source may be used as an alternative to inclusion of an AC/DC converter (p. 7, lines 13-14 and p. 15, lines 6-8). Another suggested alternative is to provide circuitry in the control module that operates on AC signals, as opposed to DC, in which case the control module could be powered directly by an AC outlet (p. 7, lines 15-16 of the instant Application).

As such, while it may be prudent to use DC power with the apparatus for the benefit of patient protection, it is not mandatory to use DC power, or to derive DC power by conversion from AC power for operation of the inventive apparatus. For this reason, Applicant respectfully

submits that it is not obvious to add an AC/DC converter to Ott, et al., and that insofar as the Examiner's rejection has been made on this basis, it should be overcome.

The Examiner states that it would be "...obvious to contain a monitoring and/or sensing means in an electrical housing..." (p. 4, para. 7 of the Official Action). Applicant's interpretation is that the Examiner believes the humidity monitoring and/or sensing means are located within the electrical housing described in the instant application (see Fig. 1, 210). Applicant respectfully points out that the specification of the instant application describes an electrical housing and a housing containing the heater/hydrator in discussing the location of components of the apparatus (see Fig. 1, 210 and Fig. 2, 138). As described in the specification, the humidity sensor is preferably located within the housing of the heater/hydrator, not within the electrical housing (p. 14, lines 19-24). In other words, the humidity monitoring means are not located within the electrical housing, and Applicant therefore needs clarification of the Examiner's statement in order to further respond to this particular rejection.

Applicant notes the Examiner's position that ...backup containers/reservoir for additional liquid would be well known in the art and/or simply a duplication of parts..., and respectfully submits that the Examiner has not given proper weight to the fact that the backup container/reservoir constitutes a component of the inventive apparatus that satisfies a long-felt need in the art. This evidence, along with commercial success, failure of others, and unexpected results, constitutes objective evidence of nonobviousness which must be considered before a conclusion of obviousness is reached. See, The Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 725 (1990). The United States Supreme Court has stated that under §103, the scope and content of the prior art are to be determined, difference between the prior art and the claims at issue are to be ascertained, and the level of ordinary skill in the pertinent art resolved, and that

such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc. that might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. See, Dennison Manufacturing Co. v. Panduit Corp., 475 U.S. 809, 810-811 (1986).

With respect to the instant application, the backup container/reservoir of the inventive apparatus satisfies a long felt need in the art to ensure that ample liquid for humidification of the gas will be available for the entire length of a given procedure. As Applicant explained in the previous response, it is impossible for a practitioner to know how much gas will actually be used during any procedure, largely because the practitioner has no control over the amount of gas that is used other than the setting of the flow rate on the insufflator that delivers the gas from the gas source. Further, a number of uncontrollable variables, such leakage of the gas through incisions, changes in surgical technique in response to a patient's anatomy, and/or the occurrence of unexpected complications during the surgery, directly affect the amount of gas that is actually required during the entire duration of a procedure. The backup container/reservoir extends the supply of humidifying solution readily available during a procedure such that the practitioner does not need to be concerned with running out of solution during a procedure, even if unexpected complications occur that delay completion of the procedure.

Concomitant to the increased use of humidified insufflation gases, a financial incentive developed to solve the problem posed by the possibility of running out of liquid for humidification of the gas prior to completion of the procedure. Despite this fact, there has been no teaching, prior to the application at issue, of the use of a backup container/reservoir on the apparatus used to humidify and otherwise condition or treat the gas. Hence, the failure of any such development constitutes a secondary indicia of nonobviousness under 35 U.S.C. §103 that

must be properly considered. Applicant respectfully submits that satisfaction of a long felt need for a backup container/reservoir in the art and the failure of any such development to occur prior, despite the financial incentive, supports the fact that it was not obvious to add a backup container/reservoir to the inventive apparatus. For this reason, the Examiner's rejection on this basis should be overcome.

The Examiner has rejected Claim 6 on the grounds that '474 teaches all the limitations of the claims except for comprising a plurality of water-retaining layers, the humidity sensing means being disposed in the chamber downstream of the heating means (p. 4, para. 8 of the Official Action). It is also the Examiner's position that it would have been obvious to one having ordinary skill in the art, at the time of invention, to add a plurality of water retaining layers to the apparatus taught by of Ott, et al ('474). As a preliminary matter, Claim 6 has been cancelled by the Applicant. Moreover, as previously discussed at length, Applicant disagrees with the Examiner's basic position that '474 teaches any humidity sensing means. Applicant does not agree that humidity sensing is taught in Col. 10 of '474, as only temperature sensing is mentioned (col. 10, lines 13-15, 37-38). There is no mention of any humidity sensing means in either the specification or the claims of '474. Further, as previously argued, Applicant is unaware of, and the Examiner has not cited to, any direct thermodynamic relationship between temperature and humidity that would control of the humidity level solely by controlling the temperature of the gas. In short, there is no support for the Examiner's conclusion that humidity sensing is taught in Col. 10 of '474.

Double Patenting

The Examiner has rejected claims 1-5, 12, 19-23, 38, 55-64, 70 and 71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,411,474 ("'474"). It is the Examiner's position that the above-listed claims are

substantially similar because '474 teaches an apparatus for treating a gas comprising a housing defining one chamber having an entry port and an exit port, the chamber that contains a volume of liquid in fluid communication with the insufflator a humidifying means, a container/reservoir, the device comprising an opening, and a port for filling the container/reservoir, and at least one layer of filter/membrane in the chamber for filtering the gas, water retaining layers and the pre-charging of those layers, use of DC power, humidity sensing means and monitoring means to sense and monitor the relative humidity of the gas and act accordingly to maintain that humidity and/or temperature, use of capacitors and resistors for the humidity sensing means, an operational amplifier, and a control means for controlling electrical power, all allowing for simultaneous heating and hydration.

Claims 12, 19-23, 38 and 55-71 have been cancelled by the Applicant, and claim 1 has been rewritten. Notwithstanding that fact, the claims set forth in the instant application describe the overall inventive apparatus, which constitutes an apparatus for treating gas received into the apparatus from an insufflator which receives gas from a gas source comprising a housing defining a chamber having humidification means disposed within the chamber for humidifying the gas, said humidification means being a subchamber within the chamber containing a volume of liquid or at least one layer of liquid-retaining material capable of retaining a volume of liquid that may be precharged with the liquid before use of the apparatus, a heating element disposed in the chamber and a temperature sensor disposed in the chamber connected to a control circuit and to the heating element to control the temperature of the gas.

As the Examiner recognizes, these claims are not identical to claims 1-15 of '474. In contravention to the Examiner's position, Applicant submits that these claims are patentably distinct from '474. These claims specify alternative embodiments of the inventive apparatus which differ with respect to the type of humidification means included in the apparatus. The instant application therefore describes specific types of humidification means that may be used in the apparatus, choice of which depends upon the type of liquid used for humidification.

Further, '474 does not contemplate treatment of the gas with any liquid other than water. The "Background of the Invention" of '474 provides that at the time of invention, insufflation gases typically were delivered to patients dry (col. 2, lines 32-33). Patent '474 improved upon the prior art by providing a high efficiency apparatus for heating, humidifying and filtering gas, allowing the gas to be delivered to a patient at an accurate temperature while also properly humidified and filtered (col. 3, lines 30-35). The instant application further improves upon the prior art, including '474, by describing humidification of the gas with various liquids and allowing the user to maintain the gas at a predetermined temperature and relative humidity level for the entire length of a procedure.

New claims 76-80 of the instant application describe the humidity sensing and monitoring means included in the inventive apparatus. Again, as previously discussed at length, Applicant disagrees that '474 teaches any humidity sensing means. In consideration of the fact that '474 does not directly teach humidity sensing, does not teach sensing or control of pressure and/or volumetric flow rate, and currently no direct thermodynamic relationship between temperature and humidity has been cited in support of the proposition that the humidity level of the gas could be controlled solely by controlling the temperature of the gas, Applicant respectfully submits that the Examiner's rejection as being unpatentable over Claims 1-15 of '474 should be overcome.

New claim 80 also relates to recharging of the container of liquid that is used for humidifying the gas. In short, these features enable the user of the inventive apparatus to replenish the supply of liquid used for humidification of the gas upon becoming alerted of the need to do so. These features necessarily involve the humidity sensing and/or monitoring means that is taught by the instant application and wholly absent from '474. As such, the instant application is therefore patentably distinct from claims 1-15 of '474, and the rejection on this basis should therefore be overcome.

The Examiner has also rejected claims 1-6, 12, 19-23, 38, 55-65, 70 and 71 as being unpatentable over claims 1-42 of U.S. Patent No. 6,068,609 ("'609"). It is the Examiner's position that the above-listed claims teach an apparatus for treating a gas comprising a housing

defining one chamber having an entry port and an exit port, the chamber that contains a volume of liquid in fluid communication with the insufflator, a humidifying means, a container/reservoir, the device comprising an opening, and a port for filling the container/reservoir, and at least one layer of filter/membrane in the chamber for filtering the gas, water retaining layers and the pre-charging of those layers, use of DC power, humidity sensing means and monitoring means to sense and monitor the relative humidity of the gas and act accordingly to maintain that humidity and/or temperature, use of capacitors and resistors for the humidity sensing means, an operational amplifier, and a control means for controlling electrical power, all allowing for simultaneous heating and hydration.

Claims 12, 19-23, 38, and 55-71 have been cancelled by the Applicant, and claim 1 has been rewritten. In addition, new claims 72-81 have been added to the application. As written, the application describes an apparatus that is used to condition gas prior to use of the gas in medical procedures, similar to the apparatus taught by '609. However, the instant application teaches features of the apparatus which are wholly absent from that of '609: conditioning the gas with liquids other than water, and a backup reservoir/container. The language of '609 limits use of the apparatus to conditioning a gas with water only prior to delivery of the gas to the patient. The instant application takes into account the fact that a user may wish to deliver agents other than water to the patient via the gas stream. In addition, the instant application claims a backup reservoir/container that ensures that the user will not run out of the humidifying solution during the entire length of a procedure. Inclusion of the reservoir/container also provides for an alternative embodiment of the apparatus that does not require use of the humidity sensing means and/or humidity monitoring means. In consideration of the fact that the instant application teaches an apparatus for conditioning gas including features that are wholly absent from the apparatus taught by '609, Applicant respectfully submits that the apparatus described by the instant application is patentably distinct from that of '609.

Finally, the Examiner has stated that Applicant failed to address the rejection raised under 35 U.S.C. 112, second paragraph, in response to the prior Official Action. In the prior Official

Action, Claims 1-31 and 52 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

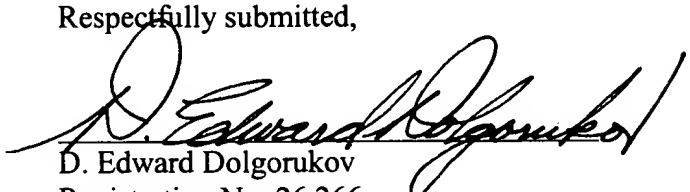
Applicant does not understand the basis for Examiner's statement. As a preliminary issue, Applicant pointed out that claims 39-54 had been previously withdrawn by the Examiner from further examination, thereby rendering the rejection of claim 52 moot. In addition, in reference to pages 3-6 of Applicant's previous response, the 35 U.S.C. 112 rejection was specifically addressed by a thorough explanation by Applicant of the exact subject matter regarded as the invention, as described by claims 1-31. For this reason, Applicant respectfully requests that the Examiner withdraw the establishment of the instant Office Action as a final action.

Further, Applicant traverses the requirement for a terminal disclaimer. Not only are the claims patentably distinct as set forth above, but the undersigned attorney wishes to bring to the attention of the Examiner that a Terminal Disclaimer would have absolutely no effect, since the present application and the ('609) patent have the same filing date, and, therefore, would have exactly the same term.

Conclusion

In view of the present amendments, and the remarks explanatory thereof, a favorable reconsideration of the present application and the passing to issue of claims 1-5 and 72-81 is courteously solicited.

Respectfully submitted,



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MARKED UP COPY

Please cancel claims 6-12, 19-23, 38, and 55-71.

Please rewrite claim 1 as follows:

1. An apparatus for [treating] conditioning gas prior to the use of the gas in a medical procedure involving a patient, the gas being received into the apparatus from an insufflator which receives gas from a gas source, and the gas exiting the apparatus being in flow communication with a means for delivering the gas to the interior of the patient, wherein the gas is pressure-and volumetric flow rate-controlled by the insufflator, the apparatus comprising:

a) a housing defining a chamber having an entry port and an exit port, the exit port adapted to be in flow communication with the means for delivering the gas and the entry port adapted to be in flow communication with [the outlet of] the insufflator; and

b) humidification means disposed within the chamber in the path of travel of the gas through the chamber for humidifying the gas as it travels through the chamber[.] ; and

c) a heating element disposed within the chamber for heating gas as it passes through the chamber; and

d) humidity sensing means disposed within the chamber for sensing the humidity of gas as it exits the chamber; and

e) monitoring means connected to the humidity sensing means for monitoring the humidity of the gas as it exits the chamber; and

f) a temperature sensor disposed in the chamber to sense the temperature of the gas as it exits the chamber; and

g) a control circuit connected to the temperature sensor and to the heating element, and responsive to the temperature sensor to control electrical power to the heating element so as to regulate the amount of heat applied by the heating element to the gas within the chamber, thereby maintaining the gas at a desired temperature or within a desired temperature range; and

h) a backup container for liquid and an access tube that couples the backup container to the housing to provide a supply of liquid to the humidification means.

Please rewrite claim 5 as follows:

5. The apparatus of claim [4] 3, wherein the at least one layer of liquid retaining material is rechargeable with liquid.

Please add the following claims:

72. The apparatus of claim 1, wherein the backup container hangs free of the housing.

73. The apparatus of claim 1, wherein the backup container is fastened to the apparatus.

74. The apparatus of claim 1, wherein the backup container is fastened to a tube segment leading from the insufflator to the entry port of the housing.

75. The apparatus of claim 1, and further comprising an extension tube that couples the access tube to the humidification means.

76. The apparatus of claim 1, wherein the humidity sensing means is positioned in the chamber in the flow path of the gas proximate the exit port of the housing.

77. The apparatus of claim 1, wherein the humidity sensing means is a humidity sensitive capacitor or a humidity sensitive resistor.

78. The apparatus of claim 1, wherein the monitoring means is responsive to a signal representing a capacitance or resistance of the humidity sensing means.

79. The apparatus of claim 1, wherein the monitoring means determines when the relative humidity of gas in the chamber drops below a relative humidity threshold and generates a signal in response thereto.

80. The apparatus of claim 1, wherein the monitoring circuit determines that the container in the humidification means requires recharging of liquid when the humidity of the gas in the chamber drops below a relative humidity threshold.

81. An apparatus for conditioning gas prior to the use of the gas in a medical procedure involving a patient, the gas being received into the apparatus from an insufflator which receives gas from a gas source, and the gas exiting the apparatus being in flow communication with a

means for delivering the gas to the interior of the patient, wherein the gas is pressure-and volumetric flow rate-controlled by the insufflator, the apparatus comprising:

a) a housing defining a chamber having an entry port and an exit port, the exit port adapted to be in flow communication with the means for delivering and the entry port adapted to be in flow communication with the outlet of the insufflator; and

b) humidification means disposed within the chamber in the path of travel of the gas through the chamber for humidifying the gas as it travels through the chamber; and

c) a heating element disposed within the chamber for heating gas as it passes through the chamber;

d) a temperature sensor disposed in the chamber to sense the temperature of the gas as it exits the chamber; and

e) a control circuit connected to the temperature sensor and to the heating element, and responsive to the temperature sensor to control electrical power to the heating element so as to regulate the amount of heat applied by the heating element to the gas within the chamber, thereby maintaining the gas at a desired temperature or within a desired temperature range; and

f) a backup container for liquid and an access tube that couples the backup container to the housing to provide a supply of liquid to the humidification means.